

REMARKS

The only issues outstanding in the Final Rejection mailed November 20, 2007, are the rejections under 35 U.S.C. 103. Reconsideration of these issues, in view of the following discussion, is respectfully requested.

Claims 5, 7-8 and 10-11 remain rejected under 35 U.S.C. 103 over Giberson and Anderson taken with Essenfeld. Claim 4 has also been rejected over Giberson, Anderson and Essenfeld further in view of Kearns. Moreover, claims 6 and 9 have been rejected under 35 U.S.C. 103 over Giberson, Anderson and Essenfeld taken with Boyce. Reconsideration of each of these rejections is respectfully requested.

As will be recalled, Giberson teaches "fixation" of tissue, e.g., with a solution containing formalin. As is well understood in the art, "fixation" does not remove any component from the tissue, but preserves the tissue as such. Clearly, the reference does not teach decellularization *as the term is understood in the art*, i.e., rupturing cells and removing cellular membranes, nucleic acids, lipids and/or pseudoplastic components so as to produce materials comprised of extracellular matrix of the tissue. See, for example, Livesey '616.

Anderson, disclosing tissue welding, also does not suggest decellularization, either alone or in combination with Giberson. Tissue welding also preserves the tissue, as would be desirable, even necessary, in order to achieve the goals of Anderson, i.e., promoting wound healing. See column 1, lines 13-16, and column 2, lines 19-22, where it is noted that it is necessary to limit tissue damage such as denaturation.

In the present invention, the tissue is treated for the purpose of preparing a scaffold material used in the field of regenerative medical technology.

Since the treated tissue is surgically grafted to a recipient, it is imperative for the tissue to be essentially free from immunogenicity, i.e., essentially free from any residual cellular component. Thus, Giberson or Anderson teaches away the treatment according to the present invention.

Essenfeld also teaches away the treatment according to the present invention. The steps of fixation, dehydration, clearing and impregnation of the process of Essenfeld preserves all cellular components in the tissue although water and fats are removed.

The Final Rejection argues that "decellularization" could read on a loss of as little as one

cell. Such a definition is not one understood in the art, and the adoption of definitions which are strained and contrary to accepted understanding in the art is not permissible. See, for example, *In re Marzocchi*, 439 F.2d 220, 169 USPQ 367 (CCPA 1971). However, in order to further clarify the claim, independent claim 10 has been amended in order to indicate that decellularization is continued until essentially no residual cell nuclei are observed on microscopic examination of the tissue. This language is clearly supported in the present specification in paragraph 24, and in Figure 2, showing decellularization even in deep interior portions of tissue as evident from the photograph. It is noted that, while the language is not necessarily found in the specification, the added claim language clearly describes what is seen in Figure 2. Where a concept is clearly disclosed in the specification, *ipsis verbis* written description is not required. See, for example, *In re Wertheim et al.*, 541 F.2d 257, 191 U.S.P.Q. 90 (CCPA 1976), and *Kennecott v. Kyocera*, 835 F.2d 1419, 5 U.S.P.Q. 2d 1194 (Fed. Cir. 1987).

It is therefore respectfully submitted that the references, whether singly or in combination, fail to suggest the presently claimed process, and withdrawal of the rejection is respectfully requested.

Should the Examiner have any questions or comments, he is cordially invited to telephone the undersigned at the number below.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-3402.

Respectfully submitted,

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